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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,421	01/11/2002	Denise R. Barbut	239/163	1910
34263	7590	11/28/2003	EXAMINER	
O'MELVENY & MEYERS 114 PACIFICA, SUITE 100 IRVINE, CA 92618			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	3
DATE MAILED: 11/28/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/045,421

Applicant(s)

BARBUT, DENISE R.

Examiner

Patricia M Bianco

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3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10-19 and 21-28 is/are rejected.
- 7) ☒ Claim(s) 7, 9 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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**DETAILED ACTION*****Specification***

Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarify the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the cooler disposed within the lumen of the tubular member, as claimed in claim 8, lacks antecedent basis in the specification.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-6, 8, 10-19, & 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khorasani (4,979,937) in view of Lewis et al. (6,436,087). Khorasani discloses a method and apparatus for providing circulation to the intercostals lumbar area during aortic surgery via intercostals perfusion tubular members. The apparatus comprises a tubular member 12 having first and second ends with a lumen between. A plurality of side members 14/36 are attached to the tubular member at a second end, each branch 36 defines a lumen. The branches have narrowed tips 50 that are sized and shaped to fit snugly into the intercostals arteries of the patient undergoing surgery. Each tip is thin and expands to form a seal with the inner wall of the intercostals artery it is disposed within. Therefore, it is considered to be expandable and equivalent to applicant's balloon occluders. The tip is sufficiently sharp to facilitate piercing the vessel wall. During use, the tubular member is inserted into a lumbar or spinal artery and the branches are inserted to provide blood perfusion to avoid ischemia of the spinal cord. The aorta is opened (i.e. slit) to allow the side members to be inserted into the intercostals. Khorasani further teaches that the system and method may be used with a bypass machine to provide oxygenated blood, using a pump, from an artery to the intercostals for perfusion. It would be within the skill of the art of the user to choose a preferred artery, such as the aorta, and said choice would be made on a case-by-case basis according the specific needs of the patient. With respect to the pump rate of between the range of 100 ml/min to 1000 ml/min, it would be obvious to one having skill in the art to choose a sufficient pump rate in this range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

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optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Khorasani discloses the invention substantially as claimed, however, fails to disclose specifically that the extracorporeal system and method includes a cooler for cooling the oxygenated medium, a cooler within the tubular member, and wherein the medium is blood cooled to between 4 degrees C and 35 degrees C.

Lewis et al. discloses a perfusion system and method for treating ischemia wherein the blood is cooled extracorporeally. Lewis also teaches that the blood or other oxygenated medium may be cooled to a temperature in the range from 2 degrees C to 36 degree. C., in order to cool and preserve the tissue. (See fig. 14 & disclosure) Cooling may be effected externally as part of the extracorporeal pumping system with a cooler or a cooler on the catheter itself. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method of Khorasani to include a cooler as part of the bypass system as taught by Lewis et al., since it Lewis teaches that a modification is desirable because cooling the blood or perfusate will preserve the tissue.

#### ***Allowable Subject Matter***

Claims 7, 9, & 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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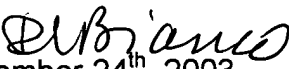
***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Crais & Rayhanabad disclose similar tubular members having a plurality of branches. Gamponia & Montanti disclose similar tubular members having balloon occluders on their ends for sealing. Sites et al., Barbut, & Barbut et al. disclose analogous extracorporeal blood perfusion systems that include cooling.

Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9306 for regular and After Final communications.

Tricia Bianco  
Patent Examiner  
Art Unit 3762

pmb   
November 24<sup>th</sup>, 2003